510(K) SUMMARY

AUG 21 2009

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

1. Submitter's Name: *digiO2 International Co., Ltd.*
Address: *4F-13, No. 79, Sec. 1, Hsin Tai Wu Rd., Hsi-Chih, Taipei Hsien 221, Taiwan*
Phone: +886-2-2698-5593
Fax: +886-2-2698-1274
Contact: Mr. Casper Chen / Title: President

2. Device Name :
Trade Name: Care Pal
Model no.: CPW-10X
Common Name: Data Management System; Accessory to Medical Device
Classification name Refer to table

Regulation Number	Classification Name	Product Code	Device Class
870.2910	Physiological Signal Transmitters and Receivers	DRG	II
862.1345	Glucose Test System	CGA	II
870.1130	Noninvasive Blood Pressure Measurement System	DXN	II
880.2700	Patient Weight Scale	FRI	I

4. Predicate Device:
- Health Buddy® with Device Connectivity **(042273)** marketed by **HEALTH HERO NETWORK, INC.**.

5. Intended Use:
Care Pal (Model no. CPW-10X) is indicated for use in non-clinical settings to collect and transmit historical medical information to healthcare professionals to help support effective management of their patients.

The product is not intended to provide automated treatment decisions nor for use as a substitute for a health care professional's judgement.

6. Device Description:

The Care Pal ("CP") remote patient monitoring system is for use in non-clinical settings as an accessory device to collect and transmit historical patient information to healthcare providers. It is intended to be used in combination with a variety of external devices. The CP remote patient monitoring system serves as the remote communication link between compatible external devices and the compatible healthcare facility at another location. The product is not intended to provide automated treatment decisions nor for use as a substitute for a health care professional's judgment.

The CP appliance contains software that can be activated to function with specific medical devices (including blood glucose meter, blood pressure and weight scale). The CP appliance with device connectivity retrieves data from a specific medical device and transmits to a remote healthcare provider using standard digital communication technologies. The CP appliance is not used directly on the patient, and poses no significant risk to the patient or other people within the patient's home.

Care Pal provides interfaces to the following connecting peripheral devices and back end server as well

a. BT
   Selected device (Brand/Model):
   weight scale, A&D/UC-321PBT

b. USB
   Selected device (Brand/Model):
   glucose meter, Johnson & Johnson LifeScan / OneTouch Ultra II (K053529)

c. RS-232 (Serial Port)
   Selected device (Brand/Model):
   blood pressure meter, A&D UA-787PC (K012013)

d. Internet (Ethernet/wireless) connection to backend server

7. Performance Summary: In terms of operating specification, Safety & EMC requirements, the device conforms to applicable standards included IEC 60601-1 and IEC 60601-1-2 requirements.

8. Conclusions:

The Care Pal (Model no. CPW-10X) has the same intended use and similar technological characteristics as the Health Buddy® with Device Connectivity **(042273)** marketed by **HEALTH HERO NETWORK, INC.**. Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, The Care Pal (Model no. CPW-10X) is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-0609
Silver Spring, MD 20993-0002

Digio2 International Co., Ltd.
c/o Ms. Jennifer Reich
Senior Consultant
Harvest Consulting Corporation
2904 N. Boldt Drive
Flagstaff, AZ 86001

AUG 21 2009

Re: K091430
Trade/Device Name: Care Pal, Model No. CPW-10X
Regulatory Number: 21 CFR 870.2910
Regulation Name: Radiofrequency Physiological Signal Transmitter and Receiver
Regulatory Class: Class II (Two)
Product Code: DRG
Dated: July 10, 2009
Received: July 15, 2009

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K091430

Indications for Use

510(k) Number (if known): K091430

Device Name: **Care Pal (Model no. CPW-10X)**
digiO2 International Co., Ltd.

Indications For Use:

Care Pal (Model no. CPW-10X) is indicated for use in non-clinical settings to collect and transmit historical medical information to healthcare professionals to help support effective management of their patients.

The product is not intended to provide automated treatment decisions nor for use as a substitute for a health care professional's judgement.

Prescription Use V AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for BZuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091430